DETAILED ACTION

Drawings

1. The corrected drawing of 4/30/2010 is acknowledged. The examiner will withdraw the outstanding objection to the previous fig. 2.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (USP 4,676,274).

4. With respect to claim 1, Brown discloses a method of controlling the transfer of one or more liquid substances from a first cavity to the second cavity (e.g. 102 and 106 respectively of fig. 12) comprising introducing a fluid into a first cavity 102 whose transfer is to be controlled and holding said liquid in the first cavity which is connected to a second cavity 106 via an intermediated cavity 104 that is filled with a gas material that prevents transfer of liquid into the intermediate cavity. See col. 8, l. 11 - col. 9, l. 21. Brown further discloses that when the intermediate cavity is then vented, the gaseous separation medium is replaced with a liquid medium in the intermediate cavity (i.e. a connecting medium). The presence of this connecting medium thereby then allows fluid transfer from the first cavity to the second cavity owing to the removal of the liquid-air junction (col. 8, ll. 22-32).

5. With respect to claim 2, the embodiment of fig. 18 utilized the device for separating cells from a fluid using mechanical pumping (col. 12, ll. 23-60).

6. With respect to claim 6, see the discussion above concerning the presence of a first cavity 102, a second cavity 106, and an intermediate cavity 104 where the intermediate cavity can hold a separation medium (gas) to hold fluid in the first cavity or a connection medium (fluid being transferred) which allows fluid to be transferred from the first cavity to the second cavity. With respect to the various limitations starting with "wherein the separation medium is replaced", these remaining limitations only further define the intended use of the device and do not further define the actual structure. The intended use need not be given further due consideration in determining patentability. However, see the discussion of claim 1 above how Brown anticipates the set forth use of the intermediate cavity.

7. With respect to claim 7, see the discussion of claim 2 above.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US 2002/0170825) in view of Brown and with or without either Sundberg et al (USP 6,090,251) or Hochstrasser (USP 4,874,490).

11. With respect to claim 1, as discussed in the previous 6/1/2009 office action, Lee discloses all the limitations of the first cavity 3, second cavity 4, but does not explicitly teach the presence of intermediate cavity that connects the first and second cavities, but does discuss that it would be desirable to control the filling of each of the cavities (i.e. microchannels) separately (e.g. par. 0043 and 0044). The previously discussed Brown teaches the use of intermediate cavities between two different cavities (i.e. capillary channels) for controlling the fluid flow from one cavity to the other. See the rejection above. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an intermediate cavity between the first and second cavities (3 and 4) of the method of Lee so that the fluid flow between the two cavities is controlled until suitable transfer between the channels is so desired.

12. This use of Brown for Lee is further rendered obvious by Sundberg which teaches that the electrophoretic channels 78 might desire different fluids than in the channel that 76 that feeds the electrophoretic channel. Sundberg suggest that a feature 90 be placed between these crossing channels such that fluid can be placed in one channel 78 without that solution bleeding into the crossing channel. See Sundberg col. 9, ll. 26-50 and compare fig. 7 of Sundberg to fig. 2 of Lee. Because Sundberg has expressed the desire for structure that permits at least temporary isolation

of one channel from a crossing channel in structure analogous to Lee, it would have been further obvious the utilize the intermediate cavity of Brown between the first and second cavities (i.e. microchannels) of the method of Lee so that fluid access to each of the channels can be separately controlled.

13. This use of Brown for Lee is further rendered obvious by the teaching of Hochstrasser which teaches in an analogous two-dimensional electrophoresis experiment that it is desired to keep the first dimension experiment isolated from the second dimensional experiment by an electrically insulating layer that can be solid, liquid, or gas (col. 2, ll. 22-39). Because Hochstrasser has expressed the desire for structure that permits electrical isolation of a first dimensional electrophoresis experiment from the chamber for performing the second dimensional experiment, it would have been further obvious the utilize the intermediate cavity of Brown between the first and second cavities (i.e. microchannels) of the method of Lee so that the second dimensional electrophoresis channels are isolated from the first dimensional electrophoresis channels during the performance of the first dimensional electrophoresis experiment.

14. With respect to claims 2 or 3, see abstract or par. 0040 of Lee.

15. With respect to claim 4, Brown already teaches that the separation substance is air and the connection medium is whatever the fluid being placed in the connected microchannels (col. 8, ll. 22-32). The fluid being placed in the channels of Lee would obviously include electroconductive fluid because electrophoresis would require charge carrying fluid.

16. With respect to claim 5, Hochstrasser teaches that the electrical isolation can be provided by materials other than air such as fluids immiscible with the materials utilized for either of the first or second dimensional experiments (col. 4, ll. 22-33).

17. With respect to claim 6, as discussed in the previous 6/1/2009 office action, Lee discloses all the limitations of the first cavity 3, second cavity 4, but does not explicitly teach the presence of intermediate cavity that connects the first and second cavities, but does discuss that it would be desirable to control the filling of each of the cavities (i.e. microchannels) separately (e.g. par. 0043 and 0044). The previously discussed Brown teaches the use of intermediate cavities between two different cavities (i.e. capillary channels) for controlling the fluid flow from one cavity to the other. See the rejection above. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize an intermediate cavity between the first and second cavities (3 and 4) in the device of Lee so that the fluid flow between the two cavities is controlled until suitable transfer between the channels is so desired.

18. This use of Brown for Lee is further rendered obvious by Sundberg which teaches that the electrophoretic channels 78 might desire different fluids than in the channel that 76 that feeds the electrophoretic channel. Sundberg suggest that a feature 90 be placed between these crossing channels such that fluid can be placed in one channel 78 without that solution bleeding into the crossing channel. See Sundberg col. 9, ll. 26-50 and compare fig. 7 of Sundberg to fig. 2 of Lee. Because Sundberg has expressed the desire for structure that permits at least temporary isolation of one channel from a crossing channel in structure analogous to Lee, it would have been further obvious the utilize the intermediate cavity of Brown between the first and second cavities (i.e.

microchannels) of the device of Lee so that fluid access to each of the channels can be separately controlled.

19. This use of Brown for Lee is further rendered obvious by the teaching of Hochstrasser which teaches in an analogous two-dimensional electrophoresis experiment that it is desired to keep the first dimension experiment isolated from the second dimensional experiment by an electrically insulating layer that can be solid, liquid, or gas (col. 2, ll. 22-39). Because Hochstrasser has expressed the desire for structure that permits electrical isolation of a first dimensional electrophoresis experiment from the chamber for the second dimensional experiment, it would have been further obvious the utilize the intermediate cavity of Brown between the first and second cavities (i.e. microchannels) of the device of Lee so that the second dimensional electrophoresis channels are isolated from the first dimensional electrophoresis channels during the performance of the first dimensional electrophoresis experiment.

20. With respect to the limitation beginning "where the separation medium is replaced…" this limitation doesn't further define the actual structure of the device, but merely define how applicant intends to utilize the structure. However, even if the examiner were to give these limitations further due consideration see the discussion of the teaching of Brown and claim 1 above.

21. With respect to claim 7, see the discussion of claim 2 above.

22. With respect to claim 8 (those limitations not covered for claim 6 above), the first cavity of Lee contains a first electrophoretic medium and the second cavity contains a second electrophoretic medium (par. 0041). Lee also discloses a plurality of voltage sources (i.e. electrodes). See par. 0030. With respect to the limitation beginning "where the separation

medium is replaced…" this limitation doesn't further define the actual structure of the device, but merely define how applicant intends to utilize the structure. However, even if the examiner were to give these limitations further due consideration see the discussion of the teaching of Brown and claim 1 above.

23. With respect to claim 9, how the connection medium is introduced doesn't not further define the actual apparatus, but merely describes how the apparatus is desired to function. This intended use need not be given further due consideration in determining patentability. However, even if the examiner were to give these further limitations further due consideration, Brown teaches that the connection medium automatically flows once the outlet of the capillary channel is vented (col. 10, ll. 18-43). This is either strongly suggestive of the use of capillary action or would have rendered obvious the use of capillary action as capillary action is a convenient passive means for causing fluid to flow through capillaries.

24. With respect to claim 10, Lee discloses introducing one or more proteins into the first cavity 3 and performing electrophoresis in the first cavity (par. 0046) and conducting electrophoresis on the one or more proteins in the second cavity (par. 0047). Furthermore, Brown teaches air can be utilized as a separation medium in an intermediate cavity when no fluid contact between two different channels is desired followed by the insertion of connecting fluid when contact is so desired (see discussion above). Because the electrophoresis experiments in cavities 3 and 4 of Lee are supposed to happen separately and preferably in electrical isolation (see Hochstrasser), it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize intermediate cavity of Brown filled with air during the first electrophoresis experiment to keep the sample in the first cavity from prematurely entering the

second cavity. After the conclusion of the first dimensional experiment, it would have been obvious to one of ordinary skill in the art to allow contact between the first and second cavities of Lee by introducing connecting medium into the intermediate cavity because at this point contact between the two different cavities is necessary to allow the sample from the first dimensional experiment to enter the second cavity for the second dimensional experiment.

25. With respect to new claims 11 and 12, see Lee par. 0034.

26. With respect to new claim 13, see Lee par. 0030.

27. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of Sundberg.

28. With respect to claims 11 and 12, Brown set forth all the limitations of the claims and suggested that the various channels of its device are capillary channels (col. 5, l. 46 – col. 6, l. 2), which would be suggestive of micrometer scaled channels. However, Brown but did not explicitly recite the channel dimensions for the device. Sundberg teaches an alternative device for controlling fluid movement through capillary channels and teaches the use of channel dimensions overlapping the claimed dimensions (col. 9, ll. 13-17). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the dimensions of Sundberg for the unspecified capillary dimensions of Brown because the utility of known capillary dimensions for analogous fluidic systems requires only routine skill in the art.

29. With respect to claim 13, Brown is drawn to controlling fluid flow through capillary channels, but does not explicitly recite the presence of electrodes. Sundberg also teaches that a conventional manner of pumping fluids through capillary channels is the use of electrokinetics, which requires at least two electrodes (col. 6, ll. 26-56). It would have been obvious to one of

ordinary skill in the art at the time the invention was being made to utilize the teaching of Sundberg for the device of Brown because electrokinetics is a well established means for moving fluids through capillary channels. Moreover as is well known in the art, electrokinetics allows for sample movement with capillary channels without the need for moving parts like mechanical pumps.

Response to Arguments

30. Applicant's arguments filed 4/30/2010 have been fully considered but they are not persuasive. With respect to the 102 rejection of claims 1 and 6, applicant urges that Brown does not disclose a connecting medium nor a replacement of a separation medium with a connecting medium as required by the present invention. The examiner disagrees as Brown discloses that when the separation medium (i.e. the gas) is removed (i.e. vented) the intermediate cavity of Brown is thereby flooded with fluid which thereby provides a fluid in the intermediate cavity. Because this fluid present in the intermediate cavity now permits fluid to flow between the first and second cavities (col. 6, ll. 3-13), this fluid thereby constitutes a "connecting medium" giving the claim language its broadest reasonable interpretation. Applicant's essential argument here appears to be that because Brown did not uniquely provides a fluid to this intermediate cavity separate from the first and second cavities, it fails to teach the provision of the claimed connecting medium. The examiner disagrees because the claims do not require the claimed connecting fluid to be a fluid unique from either of the fluids in the first and second cavities, nor do the claims require the connecting medium be delivered from somewhere other than the first and second cavities. All claim 1 requires in a broadly defined "connecting medium" replace a

separation medium and be introduced into the intermediate cavity. Brown teaches this and thereby anticipates claims 1 and 6.

31. Furthermore, claim 6 is drawn to an apparatus and the examiner explained in the previous office action that the various limitations concerning the connection medium is simply the intended use of the apparatus (see par. 8 from the 12/31/2009 office action which is also reprinted above). Hence, whatever the merits of applicant's arguments about the use of a connection medium in Brown as they pertained to claim 1, those arguments would be irrelevant for claim 6 where introducing a connecting medium after a separation medium is only how applicant intends to utilize the claimed structure. Because Brown teaches the claimed first, second, and intermediate cavities, it meets claim 6 even if Brown didn't teach the use of a connection medium.

32. With respect to Brown and claims 2 and 7, applicant urges that the embodiment of fig. 18 of Brown is external to the main device and this wouldn't meet claim 2. The examiner is confused by these arguments because Brown explicitly teaches that the various valves 309-317 for the fig. 18 device can be the valves that Brown just described for fig. 12 (col. 12, ll. 7-18). The valves shown in fig. 12 utilize an intermediate cavity 104 placed between adjacent first and second cavities (102 and 106) to control the fluid transfer between the cavities. So a cell separation occurring in one cavity in fig. 18 is separated from the other cavities of fig. 18 by a valve feature having an intermediate cavity for controlling the flow between these cavities. Hence, the intermediate cavity 104 of Brown is between all the various cavities of fig. 18 because this intermediate cavity 104 is incorporated into all the valves 309-317 to control the

fluid flow. This meets the claims giving the claim language its broadest reasonable interpretation.

33. With respect to the rejection relying on Lee in view of Brown, applicant's principle argument here appears to be that Brown fails to teach the set forth connection medium. As discussed for the 102 rejection above, this argument was already unpersuasive for claim 1 and both unpersuasive and irrelevant for claim 6.

34. Applicant further urges that one of ordinary skill in the art would not have been motivated to arrive at the present invention because Lee's device did not recognize any problem with keeping its first and second cavities separate from each other. This is unpersuasive because Sundberg recognized that orthogonal channels containing different first and second media (analogous to Lee) can benefit from a valve means between the two channels to that the fluid movement between the channels can be controlled (col. 9, l. 51 - col. 10, l. 3). Furthermore, Hochstrasser recognized that first and second electrophoretic media orthogonal to each other (analogous to Lee) should be kept separate from each other until transfer between the two is desired. Hence, Sundberg and Hochstrasser would evidence to one of ordinary skill in the art that some kind of valve means would be desirable for a device like Lee's so that these two different electrophoresis cavities could be kept separated from each another when such a separation is desired. Brown teaches a valve means that is readily adaptable to fluidic channels. Applicant further urges that Lee already discussed means for controlling fluid transfer (i.e. membranes between the cavities). However, one possible solution to keeping the two channels separate from each does not render all other possible solutions to this problem, including Brown's solution, unobvious. Moreover, Lee's solution only addresses the issue of filling the

two channels with different fluids and wouldn't prevent fluid flow between the channels after the filling (and hence during any electrophoresis experiment) because of the lack of any surface tension barrier across this membrane. The valve or barrier means of Brown provide an active valving means that would be present even when fluid is present in both of the first and second cavities.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795

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